POSSE HERRERA RUIZ

VOLUNTARY LICENSE AGREEMENTS FOR GENERIC MANUFACTURERS:

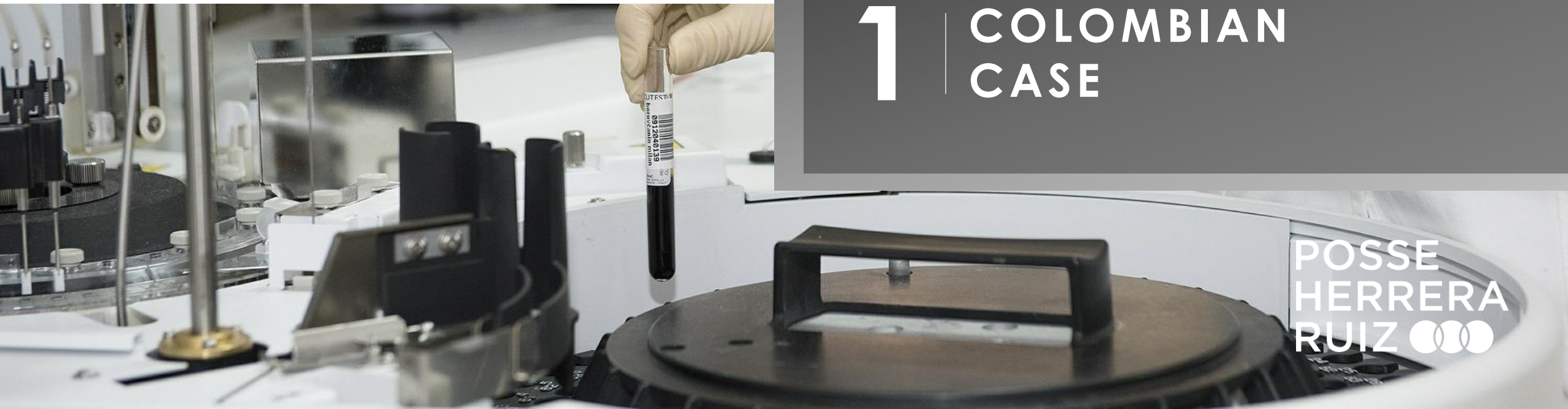
¿Are they an effective path towards improving access to medicines in developing countries?

Brief context of generic pharmaceuticals and manufacturers in Colombia

Government's efforts to reduce the lack of access to medicines

- Compulsory licenses
- Centralized purchasing or negotiation
- Price control
- Scope of rights on behalf of the Colombian PTO

Cases of voluntary licenses



1 COLOMBIAN CASE

POSSE HERRERA RUIZ

2 INTELLECTUAL PROPERTY RIGHTS VS. ACCESS TO MEDICINES IN DEVELOPING COUNTRIES

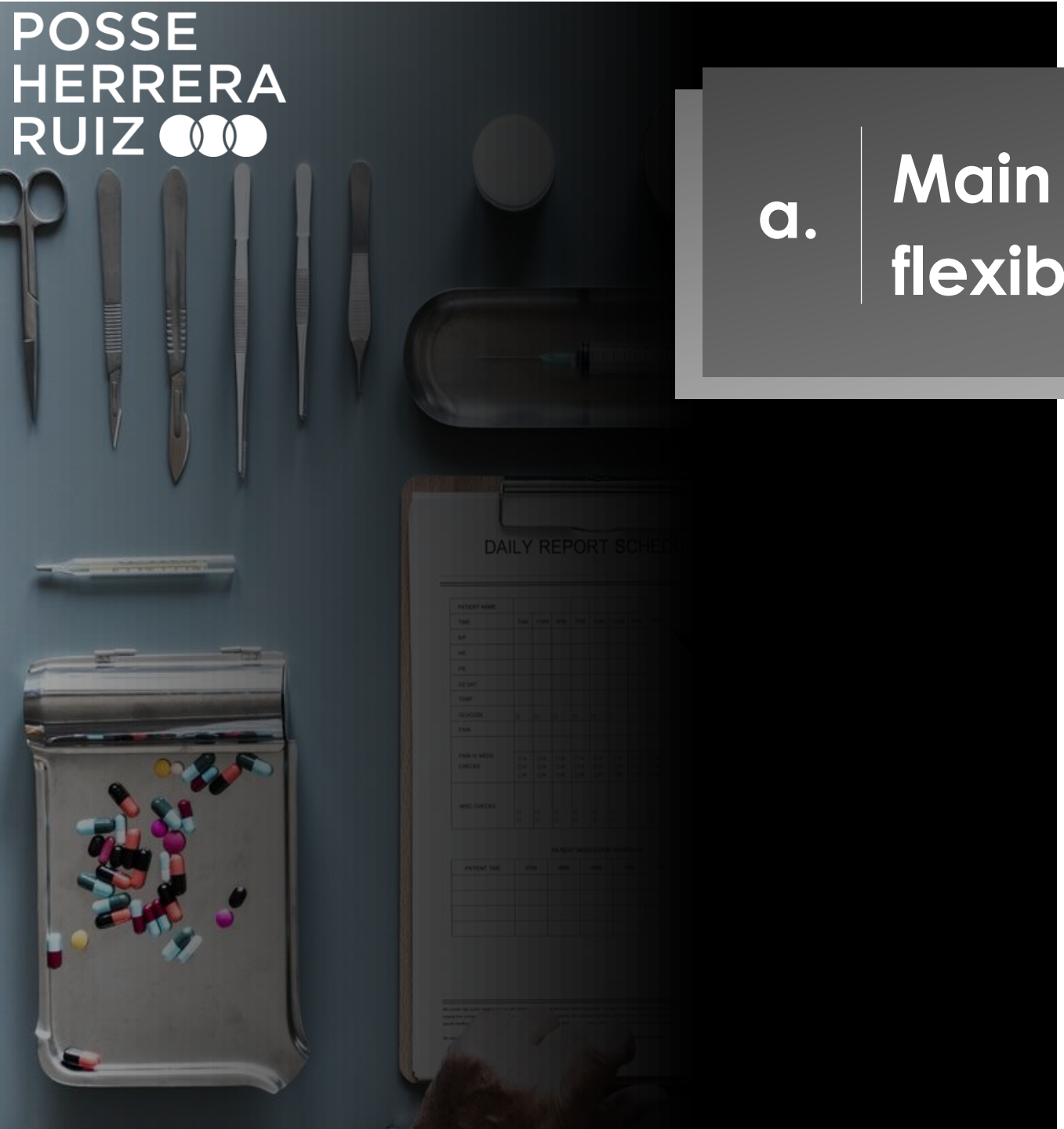
a. Legal framework: TRIPS Agreement, DOHA Declarations

b. Flexibilities in developing countries – Practical view on how can Governments implement them as a remedy to the lack of access to medicines.

c. Limitations on developing countries: voluntary license agreements as an option to improve access to medicines.

POSSE HERRERA RUIZ

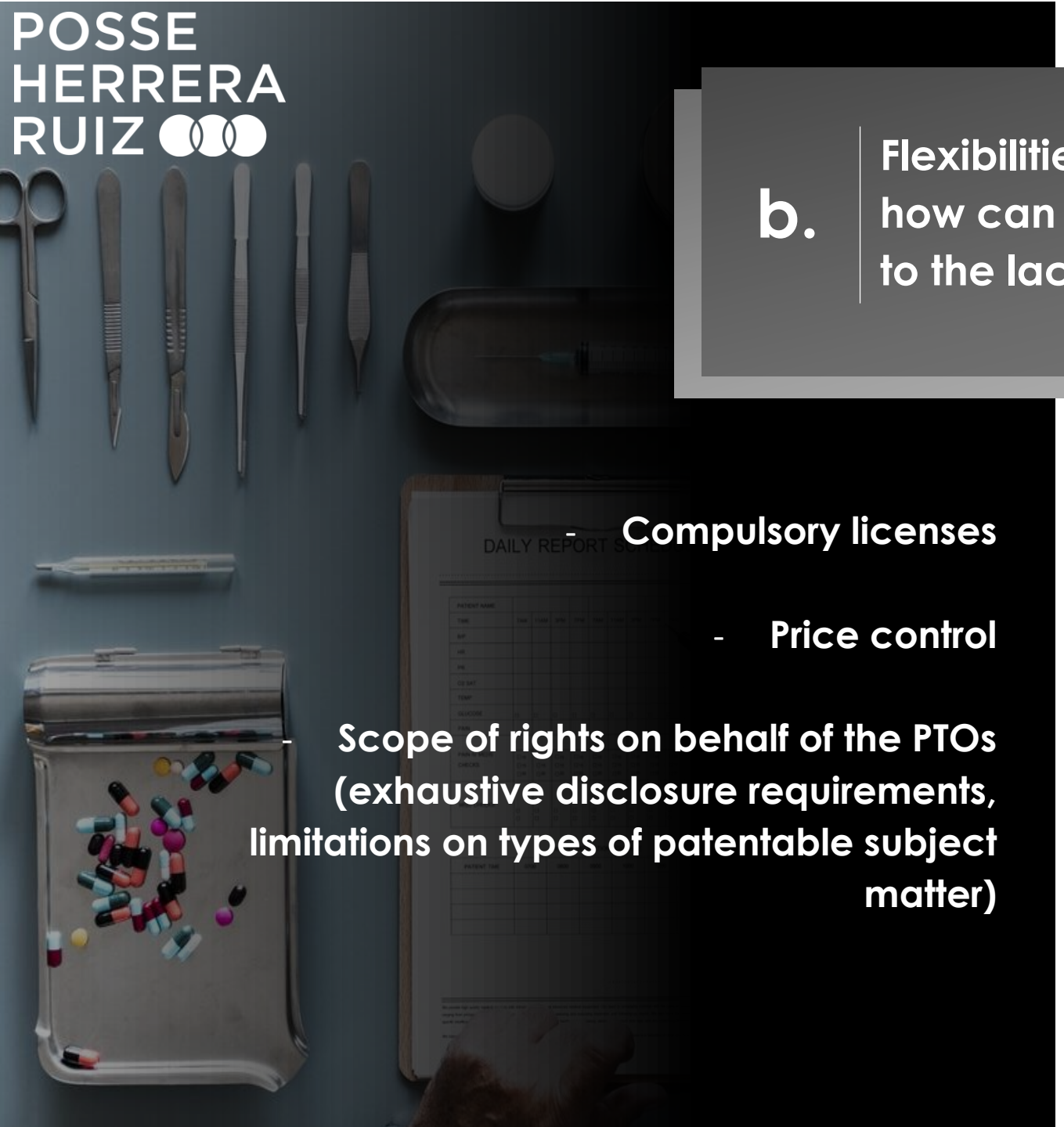
POSSE HERRERA RUIZ



a. Main legal framework of the flexibilities

- TRIPS Agreement
- DOHA Declaration
- Compulsory licenses

POSSE HERRERA RUIZ

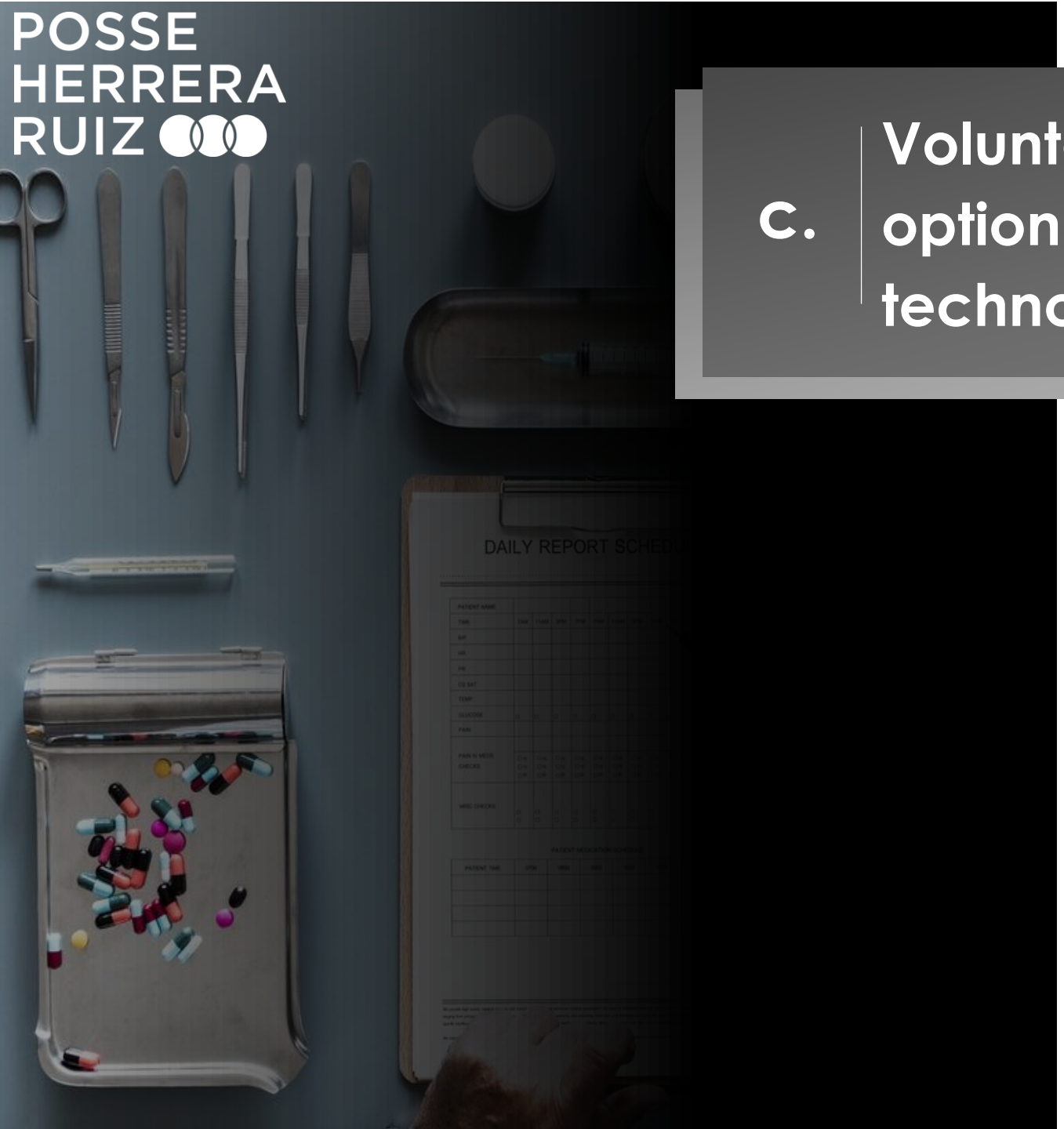


b. Flexibilities in developing countries – Practical view on how can Governments implement them as a remedy to the lack of access to medicines

- **Compulsory licenses**
- **Price control**
- **Scope of rights on behalf of the PTOs (exhaustive disclosure requirements, limitations on types of patentable subject matter)**

- Transition Periods
- Exhaustion of rights (parallel import)
- Anticompetitive practices
- Not exceeding patent terms for regulatory reasons
- Test Data (requirements from Regulatory Agencies)

POSSE HERRERA RUIZ



C. Voluntary license agreements as an option to improve transfer of technology

- Limitations
- Advantages of voluntary license agreements

POSSE HERRERA RUIZ

3 CLAUSES: CRITICAL POINTS IN VOLUNTARY LICENSE AGREEMENTS

1. Promoting access to medicines through voluntary license agreements
2. Exclusivity
3. Geographical restrictions
4. Duration

POSSE HERRERA RUIZ

3 CLAUSES: CRITICAL POINTS IN VOLUNTARY LICENSE AGREEMENTS

5. Technology transfer (disclosure)
6. Applicable sectors
7. Royalties
8. Restrictions on suppliers
9. Proprietary data

POSSE HERRERA RUIZ

CONCLUSIONS